4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0212]

Bristol-Meyers Squibb Company, et al.; Withdrawal of Approval of 19 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 19 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 009218	Coumadin (warfarin sodium) Tablets, 1 milligram (mg), 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, and 10 mg Coumadin (warfarin sodium) Injection, 5 mg/vial, 50 mg/vial, and 75 mg/vial	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543
NDA 011664	Decadron (dexamethasone) Tablets, 0.25 mg, 0.5 mg, 0.75 mg, 1.5 mg, 4 mg, and 6 mg	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., 1 Merck Dr., Whitehouse Station, NJ 08889
NDA 017481	Vermox (mebendazole) Chewable Tablets, 100 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560
NDA 018538	Lozol (indapamide) Tablets, 1.25 mg, and 2.5 mg	Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807
NDA 018986	Pralidoxime Chloride Injection (auto-injector), 600 mg/2 milliliters (mL) (300 mg/mL)	Meridian Medical Technologies, Inc., 1945 Craig Rd., St. Louis, MO 63146
NDA 019999	Morphine Sulfate Injection (auto-injector), 10 mg/0.7 mL	Do.
NDA 020363	Famvir (famciclovir) Tablets, 125 mg, 250 mg, and 500 mg	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936-1080
NDA 020711	Zyban (bupropion hydrochloride (HCl)) Extended-Release Tablets, 100 mg, and 150 mg	GlaxoSmithKline LLC, 5 Crescent Dr., Philadelphia, PA 19112
NDA 020809	Diclofenac Sodium Ophthalmic Solution, 0.1%	Alcon Research, LLC, 6201 South Freeway, Fort Worth, TX 76134
NDA 021713	Abilify (aripiprazole) Oral Solution, 1 mg/mL	Otsuka Pharmaceutical Co., Ltd. c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850
NDA 021729	Abilify (aripiprazole) Discmelt Orally Disintegrating Tablets, 10 mg, 15 mg, 20 mg, and 30 mg	Do.
NDA 021866	Abilify (aripiprazole) Injection, 9.75 mg/1.3 mL (7.5 mg/mL)	Do.
NDA 022024	Actoplus Met XR (metformin HCl and pioglitazone) Extended-Release Tablets, 1gram (g)/Equivalent to (EQ) 15 mg base and 1 g/EQ 30 mg base	Takeda Pharmaceutical U.S.A. Inc., 95 Hayden Ave., Lexington, MA 02421
NDA 050605	Ceftin (cefuroxime axetil) Tablets, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base	GlaxoSmithKline Intellectual Property (no. 2) Ltd. England, c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA

Application No.	Drug	Applicant
		19426
NDA 050672	Ceftin (cefuroxime axetil) Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL	Do.
NDA 207988	Zurampic (lesinurad) Tablets, 200mg	Ironwood Pharmaceuticals, Inc., 100 Summer St., Suite 2300, Boston MA 02110
NDA 208383	Bevyxxa (betrixaban) Capsules, 40 mg and 80 mg	Portola Pharmaceuticals, Inc., 270 East Grand Ave., South San Francisco, CA 94080
NDA 210709	Tekturna (aliskiren hemifumarate) Capsules (Pellets), EQ 37.5 mg base	Nodem Pharma DAC, 4820 Emperor Blvd., Durham, NC 27703
NDA 210874	Qternmet XR (dapagliflozin, metformin HCl and saxagliptin) Extended-Release Tablets, 2.5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 5 mg base, and 10 mg/1 g/EQ 5 mg base	AstraZeneca AB, c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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